

REMARKS

The above amendment is submitted in response to the final Office Action of February 26, 2007. Currently Claims 38-60 and 73-81 are pending, with Claims 40-43, 55-59, and 77-80 having been withdrawn and all other claims standing rejected. Applicants have amended independent Claim 38 above by incorporating the limitations of Claims 52, 54 and 55. Claims 52, 54 and 55 have been cancelled accordingly. Independent Claim 73 has been amended in the same fashion as independent Claim 38. All remaining withdrawn claims are directed to nonelected species and depend from generic claims that Applicants submit to be in condition for allowance, and thus have been maintained. Reconsideration is respectfully requested.

Summary of Telephone Interview

A telephone interview between the undersigned attorney and Examiner Micah Paul Young was held on August 22, 2007. The Examiner's time and courtesy during that call are gratefully acknowledged. The proposed amendment was discussed in view of the outstanding rejections under 35 USC § 112, first paragraph, and § 103. The discussion regarding each of these rejections is summarized below. Lengthy arguments are not presented to avoid redundancy with the prior Amendment filed November 6, 2006, to which the Examiner's attention is directed. The undersigned attorney acknowledges that the Examiner indicated the above amendment would be favorably considered upon further review and appreciates the Examiner's willingness to telephone the undersigned attorney to discuss any remaining issues.

Rejection under 35 USC § 112, first paragraph

The Office Action rejected Claims 38, 39, 44-54, 59, 60, 73-76 and 81 under 35 USC § 112, first paragraph for lack of enablement, stating that while being enabled for specific compounds such as interleukin, enablement was not provided for all possible compounds defined as anabolic agents or catabolic inhibitors. In order to expedite the

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application, Applicants have amended each of the independent claims to include the specific groups of chondroprotective agents set forth in dependent claims 52, 54 and 55, and note that such agents individually are well known, characterized and assayable as evidenced by the declarations of Drs. Goldring, Lotz and Abramson previously submitted with the prior Amendment of November 6, 2006 (with commensurate arguments being provided on pages 7-15 thereof). While the present amendment is submitted in anticipation, based on the telephone interview, that it satisfies the concerns set forth in the Office Action, Applicants reserve the right to file claims of original breadth in a potential continuation application for all of the reasons set forth in the prior Amendment.

Rejection under 35 USC § 103

Claims 38, 39, 44-54, 59, 60, 73-76 and 81 stand rejected under 35 USC § 103. This rejection was discussed in the telephone interview with the Examiner, as was the disclosure of the two cited references, US Patent 6,096,728 to Collins et al. and US Patent 5,206,023 to Hunziker. While initially properly characterized in the Office Action as disclosing catabolic inhibitors, on page 7 of the Office Action Collins '728 is characterized as disclosing anabolic chondroprotective compounds. It is respectfully noted that this appears to be a typographical error, as Collins '728 discloses catabolic inhibitory agents, such as IL-1 inhibitors, and anti-inflammatory agents, but no anabolic chondroprotective agents. Thus contrary to a statement made at the top of page 6 of the Office Action, Collins '728 does not support the combination of an anabolic chondroprotective agent with an inhibitor of cartilage catabolism.

The second reference, Hunziker '023, discloses, in contrast, anabolic agents such as TGF- β , but does not disclose the use of inhibitors of cartilage catabolism. The Office Action cites the disclosure of "tumor necrosis factors (TNF alphas)" in Hunziker '023, and mistakenly characterizes these as catabolic inhibitory agents within the scope of the claimed invention.

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Applicants respectfully note that Hunziker '023 discloses at Column 7, lines 62-65, TNF- α and TNF- β , which are actually pro-inflammatory chemotactic agents, in contrast to the present invention that encompasses the use of *antagonists* or *inhibitors* of TNF- α . In other words, Hunziker '023 discloses the use of TNF- α , while the present invention encompasses the use of inhibitors of TNF- α . Thus, Hunziker '023 actually teaches away from the present invention.

Neither Collins '728, which discloses catabolic inhibitors but not anabolic chondroprotective agents, nor Hunziker '023, which discloses anabolic agents but not inhibitors of cartilage catabolism, provides motivation for combining anabolic chondroprotective agents with inhibitors of cartilage catabolism. Rather, as discussed with the Examiner, these references address two separate prior art approaches, and are consistent with a larger body of art of record which follows either one approach or the other, with a long standing failure to recognize that the approaches should be combined. Attention is directed to the prior amendment at page 18, as well as the declaration of Drs. Goldring submitted therewith, regarding this point.

During the interview it was also noted that the applicants have submitted a good variety of data on the advantages and unexpected results of the present invention, both in the declaration of Dr. Moore submitted with the prior amendment of November 6, 2006, which was acknowledged in the Office Action, but also the non-prior art references providing additional data in support of the invention (publications by Studer et al.) previously submitted and then again summarized in the prior Amendment, which was not addressed in the Office Action. All together, this collection of evidence clearly overcomes any arguable *prima facie* case of obviousness.

Information Disclosure Statement

In the Office Action of May 4, 2006, the Examiner kindly acknowledged receipt of a supplemental information disclosure received by the PTO on January 27, 2006. However, the single reference listed on the Citation of Information form (PTO form 1449) was inadvertently

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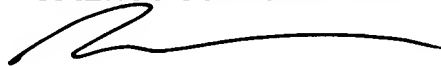
not initialed. To clarify the record, the Examiner is respectfully requested to initial and return that form (a duplicate copy of which was submitted with the Amendment of November 6, 2006), as well as the Citation of Information form attached to the supplemental information disclosure statement submitted with the prior Amendment of November 6, 2006.

Summary

Applicants respectfully request reconsideration and allowance of Claims 38-51, 53, 56-60 and 73-81, which are submitted to be in condition for allowance. The undersigned attorney would welcome a call to discuss any remaining issues.

Respectfully Submitted,

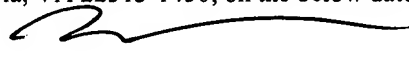
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I hereby certify that this correspondence is being deposited with the U.S. Postal Service in a sealed envelope as first class mail with postage thereon fully prepaid and addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the below date.

8/22/07
Date



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